



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/704,134      | 11/01/2000  | Todd Siegel          | 00688081            | 4080             |

33448 7590 05/04/2004

ROBERT J. DEPKE LEWIS T. STEADMAN  
HOLLAND & KNIGHT LLC  
131 SOUTH DEARBORN  
30TH FLOOR  
CHICAGO, IL 60603

EXAMINER

PARADISO, JOHN ROGER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3721

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/704,134

Applicant(s)

SIEGEL ET AL.

Examiner

John R. Paradiso

Art Unit

3721

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendments*

1. In view of the amendments filed 2/6/2004, the objections to the claims and the rejections to the claims under 35 U.S.C. § 112 are hereby withdrawn.

### *Claim Rejections*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over KNUDSEN (US 4490963) in view of BOUTHINETTE (US 6023916) and HAYES ET AL (US 6334980), as explained in the previous Office Action and reprinted below for convenience.

KNUDSEN discloses an automated pharmaceutical packaging machine in which pharmaceutical products are dispensed from an array of sources (16) into each cavity of a plurality of product package cavities (14) and transferring them into a product package member and then to a package sealer downstream. (See KNUDSEN columns 3 and 4 and figures 1 and 12.)

4. KNUDSEN does not specifically disclose the pharmaceutical products being dispensed into product package templates.

Art Unit: 3721

5. BOUTHINETTE discloses a packaging kit with product package template cavities corresponding to cavities of a product package member. (See BOUTHINETTE columns 5 and 6 and figures 2, 7, and 11.)

6. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of KNUDSEN by dispensing the pharmaceutical products into product package templates, as taught by BOUTHINETTE, in order to ensure facilitate product placement into popular compartmented containers.

7. The combination of KNUDSEN and BOUTHINETTE does not disclose the use of an X-Y mechanical drive to move the package templates.

8. HAYES ET AL discloses an apparatus in which a dispensing apparatus (602a-c) which dispenses specific quantities of fluid to specific places on a template (722) which is moved by an X-Y positioning table (606). An X-Y (608) moves the positioning table so that the correct spots in the template are positioned under the correct dispensers. (See HAYES ET AL column 11 line 38 to column 12 line 19 and figure 9.)

9. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the X-Y positioning table, as taught by HAYES ET AL, in the combination of KNUDSEN and BOUTHINETTE in order to more accurately place the products.

10. Regarding claims 2 and 7, Applicant is given Official Notice that the use of pneumatic cylinders for movement of machine assemblies is notoriously well known in the art and it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pneumatic cylinders to move the parts of the combination of KNUDSEN, BOUTHINETTE, and HAYES ET AL in order to move the assemblies in an easily controllable manner.

11. Regarding claims 3 and 8, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the combination of KNUDSEN, BOUTHIETTE, and HAYES ET AL with any number of arrays and funnels, as determined to be most efficient, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

12. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over TAKEMASA ET AL (US 5765606) in view of BOUTHIETTE (US 6023916) and HAYES ET AL (US 6334980), as explained in the previous Office Action and reprinted below for convenience.

13. TAKEMASA ET AL discloses an automated pharmaceutical packaging machine in which pharmaceutical products are dispensed from an array of sources (7) into each cavity of a plurality of product package cavities (33) and transferring them into a product package member. (See TAKEMASA ET AL columns 4 and 5 and figure 6.)

14. TAKEMASA ET AL does not specifically disclose the pharmaceutical products being dispensed into product package templates.

15. BOUTHIETTE discloses a packaging kit with product package template cavities corresponding to cavities of a product package member. (See BOUTHIETTE columns 5 and 6 and figures 2, 7, and 11.)

Art Unit: 3721

16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of TAKEMASA ET AL by dispensing the pharmaceutical products into product package templates, as taught by BOUTHINETTE, in order to ensure facilitate product placement into popular compartmented containers.

17. The combination of TAKEMASA ET AL and BOUTHINETTE does not disclose the use of an X-Y mechanical drive to move the package templates.

18. HAYES ET AL discloses an apparatus in which a dispensing apparatus (602a-c) which dispenses specific quantities of fluid to specific places on a template (722) which is moved by an X-Y positioning table (606). An X-Y (608) moves the positioning table so that the correct spots in the template are positioned under the correct dispensers. (See HAYES ET AL column 11 line 38 to column 12 line 19 and figure 9.)

19. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the X-Y positioning table, as taught by HAYES ET AL, in the combination of TAKEMASA ET AL and BOUTHINETTE in order to more accurately place the products.

20. Regarding claims 2 and 7, Applicant is given Official Notice that the use of pneumatic cylinders for movement of machine assemblies is notoriously well known in the art and it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pneumatic cylinders to move the parts of the combination of KNUDSEN, BOUTHINETTE, and HAYES ET AL in order to move the assemblies in an easily controllable manner.

21. Regarding claims 3 and 8, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the combination of KNUDSEN, BOUTHINETTE, and HAYES ET AL with any number of arrays and funnels, as determined to be most efficient, since

it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Response to Arguments***

22. Applicant's arguments filed 2/6/2004 have been fully considered but they are not persuasive.

23. Applicant states on page 6 of his Response that "Applicants note that the Bouthiette reference is merely directed to a manual kit that is used to sort pills, tablets or capsules. The pill-sorting device disclosed in this reference is made of two sliding panels with hollow bottom recesses that can [be] used to insert the pills into the containers of the container-defining sheet."

However, BOUTHETTE was used in the rejections above to teach the use of the templates with cavities for the articles.

24. Applicant states on page 6 of his Response that "this [BOUTHETTE] is merely a manual mechanism."

However, as explained above, BOUTHETTE was used in the rejections above to teach the use of the templates with cavities for the articles. Examiner further notes that it has been held that broadly providing a mechanical or automatic means to replace manual activity which

has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 199.

25. Applicant states on page 6 of his Response that “the Bouthiette reference similarly as with the Knudsen reference fails to provide any teaching or suggestion whatsoever regarding the use of an X-Y mechanical drive for manipulating product package members as claimed.”

However, these references were not used for that teaching – HAYES ET AL was used to teach this feature, as explained above.

26. Applicant states on page 7 of his Response that “Hayes merely is directed to an apparatus for conducting biochemical reactions and analysis...” and “is non-analogous art”.

27. However, it is misleading to say that HAYES ET AL is merely an apparatus for conducting research and analysis without examining the structure and functions disclosed therein. In particular, HAYES ET AL shows a dispensing apparatus (602a-c) which dispenses specific quantities of fluid to specific places on a template (722) which is moved by an X-Y positioning table (606). An X-Y (608) moves the positioning table so that the correct spots in the template are positioned under the correct dispensers. (See HAYES ET AL column 11 line 38 to column 12 line 19 and figure 9.) Accordingly, Examiner maintains the rejections detailed above.

In response to applicant's argument that HAYES ET AL is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977



F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, HAYES ET AL is concerned with dispensing pharmaceutical dosages into a template.

***Conclusion***

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



**EUGENE KIM  
PRIMARY EXAMINER**

Art Unit: 3721

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Paradiso. The examiner can normally be reached Monday-Friday, 9:30 p.m. – 6:00 p.m. (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada, can be reached at the number listed below.

Any inquiry of a general nature or relating to the status of this application should be directed to the 3700 Technology Center Receptionist.



Examiner John Paradiso: (703) 308-2825

April 27, 2004

***Additional Phone Numbers:***

Supervisor Rinaldi Rada: (703) 308-2187  
TC 3700 Receptionist: (703) 308-1148  
Customer Service: (703) 306-5648  
Fax (directly to Examiner) (703) 746-3253  
Fax (Official): (703) 872-9306



EUGENE KIM  
PRIMARY EXAMINER